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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/722,000

11/25/2003

Peter L. Collins

NIHB-2264

6530

45160 7590 10/20/2009

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

10/20/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/722,000 | <b>Applicant(s)</b><br>COLLINS ET AL. |  |
|                              | <b>Examiner</b><br>Zachariah Lucas   | <b>Art Unit</b><br>1648               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,18-20,22-24,28,35-48,64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) 37-45,64 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,18-20,22-24,28,35,36 and 46-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1, 4, 18-20, 22-24, 28, 35-48, 64, and 65 are pending in the application.
2. In the prior action, mailed on January 30, 2009, claims 1, 4-11, 14-20, 22-33, 35-48, 52, and 55-65 were pending in the application; with claims 5-11, 15-17, 25-27, 29-33, 37-45, 52, and 55-65 withdrawn from consideration; and claims 1, 4, 14, 18-20, 22-24, 28, 35, 36, and 46-48 under consideration and rejected.
3. In the Response of September 8, 2009, correcting informalities in the response of May 29, 2009, the Applicant amended claims 1 and 64; and cancelled claims 5-11, 14-17, 25-27, 29-33, 52, and 55-63.
4. Claims 1, 4, 18-20, 22-24, 28, 35, 36, and 46-48 are under consideration.

### ***Priority***

5. **(Prior Objections- Withdrawn)** Several objections were raised with respect to the priority statement(s) on page 1 of the application. In view of the amendments, the objections are withdrawn.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **(Prior Rejection- Maintained)** Claims 1, 4, 14, 18, 19, 22-24, 28, 35, 36, and 46-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (U.S. 5,840,520) and Collins (PNAS 92: 11563-67), and Murphy et al. (U.S. 5,922,326), and further in view of Wertz et al. (U.S. 5,789,229). The rejection is maintained over pending claims 1, 4, 14, 18, 19, 22-24, 28, 35, 36, and 46-48. Claim 14 has been cancelled from the application. The rejection is therefore withdrawn from this claim. Claim 1 has been amended to incorporate the limitations of claim 14. In particular, the claim has been amended to specify the presence of the amino acid substitutions to the L protein indicated to be responsible for the attenuation of the cpts RSV 248 or 1030 viruses. See, the teachings of Firestone and Whitehead as cited on page 8 of the action mailed on January 19, 2007.

The Applicant traverses the rejection on substantially the same grounds as indicated in the response of October 2008. The Applicant additionally asserts that the Examiner's reliance on the KSR decision is misplaced as there would have been an unacceptably large number of potential solutions to the problem in the present instance. This argument is not found persuasive as the Examiner does not agree that there would have been an unacceptably large number of potential solutions. In the present instance, the question is not what specific mutations would be required to make the 248, 1030, and the combination mutation, but what insertions suggested by Clarke could be made into the already mutated viruses of Murphy so as to obtain an attenuated RSV having the heterologous gene. The number of potential solutions reflects the genes to be inserted, not the positions of the mutations as the knowledge of the mutation positions would not be required for the making of the attenuated viruses comprising the insertions. The Applicant's arguments are therefore not found persuasive for the reasons above, and the reasons of record.

8. **(Prior Rejection-Maintained)** Claim 20 was rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke, Collins, Murphy, and Wertz as applied above, and further in view of the teachings of Connors et al. (Virology 208:478-84- reference CH in the July 2008 IDS) and Randolph et al. (US 5,932,222). Applicant traverses this rejection on the same grounds asserted with respect to claims 1, 4, 18, 19, 22-24, 28, 35, 36, and 46-48 above. The argument is not found persuasive for the reasons indicated above.

***Double Patenting***

9. **(Prior Rejection- Withdrawn)** Claims 1, 4, 14, 18, 19, 20, 22-24, 28, 35, and 46-48 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 12, 14, 18, 20-25, 28, and 31-34 of U.S. Patent No. 6,689,367. In view of the terminal disclaimer of May 29, 2009, the rejection is withdrawn.

***Conclusion***

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/  
Primary Examiner, Art Unit 1648